

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today  
(1) was not written for publication in a law journal and  
(2) is not binding precedent of the Board.

Paper No. 29

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte JONATHAN S.H. DENYER  
and KEVEN MC GUINNESS

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Appeal No. 99-0230  
Application 08/396,277<sup>1</sup>

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ON BRIEF

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Before COHEN, ABRAMS, and HAIRSTON, Administrative Patent Judges.

ABRAMS, Administrative Patent Judge.

**DECISION ON APPEAL**

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<sup>1</sup>Application for patent filed February 28, 1995.  
According to appellants, this application is a continuation of  
Application No. 08/117,402, filed September 3, 1993.

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This is an appeal from the decision of the examiner finally rejecting claims 1-3 and 6-12, which constitute all of the claims remaining of record in the application.

The appellants' invention is directed to an apparatus and method for delivering an aerosol drug to the respiratory system of a patient. The claims on appeal have been reproduced in an appendix to the Brief.

#### **THE REFERENCES**

The references relied upon by the examiner to support the final rejection are:

|                      |           |         |
|----------------------|-----------|---------|
| Edgar et al. (Edgar) | 4,677,975 | Jul. 7, |
| 1987                 |           |         |

|                      |           |         |
|----------------------|-----------|---------|
| Snook et al. (Snook) | 4,938,212 | Jul. 3, |
| 1990                 |           |         |

|                              |         |          |
|------------------------------|---------|----------|
| Henry (European Application) | 461,281 | Dec. 18, |
| 1991                         |         |          |

Murray et al. Textbook of Respiratory Medicine, Volume 1, Second Edition, 1988, pp. 361-362 (the textbook)

#### **THE REJECTIONS**

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Claims 1-3 and 6-12 stand rejected under 35 U.S.C. § 103 as being unpatentable over Edgar in view of Henry, the textbook, and Snook.

Claims 11 and 12 stand rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Henry.

#### OPINION

Rather than attempt to reiterate the examiner's full commentary with regard to the above-noted rejections and the conflicting viewpoints advanced by the examiner and the appellants regarding the rejections, we make reference to the final rejection (Paper No. 23) for the reasoning in support of the rejections, and to the Appellant's Brief (Paper No. 27).

#### *The Rejection Under 35 U.S.C. § 103*

The test for obviousness is what the combined teachings of the prior art would have suggested to one of ordinary skill in the art. See, for example, ***In re Keller***, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In establishing a *prima facie* case of obviousness, it is incumbent upon the examiner to provide a reason why one of ordinary skill in the art would

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have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. See ***Ex parte Clapp***, 227 USPQ 972, 973 (Bd. Pat. App. & Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from the appellant's disclosure. See, for example, ***Uniroyal, Inc. v. Rudkin-Wiley Corp.***, 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1439 (Fed. Cir.), *cert. denied*, 488 U.S. 825 (1988).

The appellants' invention is directed to an arrangement for enhancing the delivery of a drug aerosol issuing from a nebulizer into an airstream that is inhaled by the patient through duct means. An objective of the invention is to enhance the operation of the system by causing the nebulizer to generate the aerosol selectively during the inhalation phase of the patient's breathing cycle. In the appellants' system, turbulence is generated in the airstream duct, and its level is measured by a microphone as an indication of the level of flow. As manifested in independent apparatus claim 1, the elements of the invention include

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means for generating turbulence in said airstream  
due to inhalation by the patient;

a microphone selectively responsive to said  
turbulence due to inhalation to generate a control  
signal; and

control means coupled to said nebulizer means and  
responsive to said control signal to cause said  
nebulizer means to generate said aerosol . . . .

Independent method claim 11 includes these same limitations.

All of the claims stand rejected as being unpatentable  
over the combined teachings of Edgar, Henry, the textbook, and  
Snook. We do not agree, and we therefore will not sustain the  
Section 103 rejection. Our reasoning follows.

Edgar discloses a drug delivery arrangement in which  
inhalation by the patient is sensed by a spring-mounted device  
mounted in the airstream delivery duct means, which senses  
that an appropriate airstream is being pulled through the duct  
by being deflected from its at rest position, whereupon it  
provides a signal to the nebulizer to inject the drug into the  
airstream. Edgar fails to disclose the required turbulence  
generating means and the microphone that reacts to the noise  
caused thereby, which in the appellants' system is indicative  
of the level of flow of the airstream through the duct during  
the patient's inhalation.

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Henry also is directed to an inhalation device in which the introduction of an aerosol drug from a nebulizer is controlled in reliance upon a specific level of air flow during inhalation. In the Henry system, a piezoelectric film sensor is placed in a secondary duct through which the patient also inhales, and it generates a signal proportional to the level of inhalation air flow therein, which is used to actuate the nebulizer. As we understand the examiner's position, it is that the Henry piezoelectric film sensor is a microphone, and that it reacts to mechanical shock or vibration in the airstream, which constitutes turbulence (see Paper No. 23, page 4). We cannot agree with this conclusion. First of all, there is no mention in Henry of turbulence being created in the passage in which the piezoelectric sensor is located. However, even if the presence of turbulence is assumed, the examiner's statements are contradicted by the common definitions known in the art, which are that a piezoelectric device generates a signal by virtue of being deformed, whereas a microphone converts sound waves, especially speech and

music, into a signal.<sup>2</sup> From our perspective, therefore, Henry would not have suggested to one of ordinary skill in the art that a microphone be utilized to indicate the level of air flow in an inhalation airstream by measuring the sound produced by turbulence in the airstream. This being the case, Henry does not alleviate the deficiency in Edgar pointed out above.

Nor is this deficiency cured by the textbook or Snook. The textbook is cited for its teaching that inhalers and nebulizers are functional equivalents in the respiratory therapy art, a conclusion that is not disputed by the appellants. It provides no information at all regarding measuring the airstream flow in a duct during patient inhalation. Snook teaches that a wide variety of sensors can be used to sense the level of flow in an aerosol delivery system. Be that as it may, Snook does not disclose or teach the claimed means for generating turbulence and the microphone. We note here in passing that while the examiner's position appears to be that the teachings of Snook would give

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<sup>2</sup>See The Illustrated Dictionary of Electronics, Fifth Edition, 1991, pp. 335-336 and 460.

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the artisan *carte blanche* to substitute any sensor for the one disclosed in Edgar, that is not the case, for the mere fact that the prior art structure could be modified does not make such a modification obvious unless the prior art suggests the desirability of doing so.<sup>3</sup> Here, the examiner has not stated, nor do we perceive, any teaching, suggestion or incentive which would have led one of ordinary skill in the art to select one particular sensor over the others to replace the one disclosed in Edgar.

It is our opinion that the teachings of the applied references fail to establish a *prima facie* case of obviousness with regard to claims 1 and 11.

*The Rejection Under 35 U.S.C. § 102(b)*

Anticipation is established only when a single prior art reference discloses, either expressly or under the principles of inherency, each and every element of the claimed invention. See ***In re Paulsen***, 30 F.3d 1475, 1480-1481, 31

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<sup>3</sup>See ***In re Gordon***, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984).



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USPQ2d 1671, 1675 (Fed. Cir. 1994) and *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990). In the present case, while Henry discloses much of the structure recited in claims 11 and 12, we agree with the appellants that it does not disclose all of it. This being the case, we will not sustain this rejection.

The pivotal issue here again is the absence of a teaching in Henry of using a microphone to measure the level of turbulence in the inhalation airstream. As explained above, we find this to be lacking in Henry, and therefore it is not anticipatory of claims 11 and 12.

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**SUMMARY**

Neither rejection is sustained.

The decision of the examiner is reversed.

**REVERSED**

|        |                             |   |               |
|--------|-----------------------------|---|---------------|
|        | Irwin Charles Cohen         | ) |               |
|        | Administrative Patent Judge | ) |               |
|        |                             | ) |               |
|        |                             | ) |               |
|        |                             | ) |               |
|        | Neal E. Abrams              | ) | BOARD OF      |
| PATENT |                             | ) |               |
|        | Administrative Patent Judge | ) | APPEALS AND   |
|        |                             | ) | INTERFERENCES |
|        |                             | ) |               |
|        |                             | ) |               |
|        | Kenneth W. Hairston         | ) |               |
|        | Administrative Patent Judge | ) |               |

tdc

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Christensen, O'Connor, Johnson & Kindness  
1420 Fifth Avenue  
Suite 2800  
Seattle, WA 98101